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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,516	06/29/2004	Peter Charles Astles	X-14685	1432
25885	7590	03/03/2006	EXAMINER	
ELI LILLY & COMPANY PATENT DIVISION P.O. BOX 6288 INDIANAPOLIS, IN 46206-6288			RAHMANI, NILOOFAR	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/500,516	Applicant(s) ASTLES ET AL.	
	Examiner Niloofer Rahmani	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,8-18,23-29,31-47 and 56-71 is/are rejected.
- 7) ☒ Claim(s) 2,7,19-22,30 and 48-55 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>06/29/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-71 are pending.

2. ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-71, drawn to compounds, pharmaceutical compositions of compounds and method of using the compounds, wherein $A=(CH_2)_q$, $q=2$, $p=o=zero$, and $m=n=1$, classified in class various, subclass various, depending on species election. If this group is elected, a further election of a single disclosed species is also required.

II. Claims 1-71, drawn to compounds, pharmaceutical compositions of compounds and method of using the compounds, wherein $A=(CH_2)_q$, $q=2$, p, o, m, n being other than as in group I, classified in class various, subclass various, depending on species election. If this group is elected, a further election of a single disclosed species is also required.

III. Claims 1-71, drawn to compounds, pharmaceutical compositions of compounds and method of using the compounds, wherein $A=(CH_2)_q$, $q=1$, $p=o=zero$, and $m=n=1$, classified in class various, subclass various,

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depending on species election. If this group is elected, a further election of a single disclosed species is also required.

IV. Claims 1-71, drawn to compounds, pharmaceutical compositions of compounds and method of using the compounds, wherein $A=(CH_2)_q$, $q=1$, p, o, m, n being other than as in group III, classified in class various, subclass various, depending on species election. If this group is elected, a further election of a single disclosed species is also required.

V. Claims 1-71, drawn to compounds, pharmaceutical compositions of compounds and method of using the compounds, wherein $A=(CH_2)_q$, $q=3$, $p=o=zero$, and $m=n=1$, classified in class various, subclass various, depending on species election. If this group is elected, a further election of a single disclosed species is also required.

VI. Claims 1-71, drawn to compounds, pharmaceutical compositions of compounds and method of using the compounds, wherein $A=(CH_2)_q$, $q=3$, p, o, m, n being other than as in group V, classified in class various, subclass various, depending on species election. If this group is elected, a further election of a single disclosed species is also required.

VII. Claims 1-71, drawn to compounds, pharmaceutical compositions of compounds and method of using the compounds, wherein $A=(CH_2)O(CH_2)$, classified in class various, subclass various, depending on species election. If this group is elected, a further election of a single disclosed species is also required.

VIII. Claims 1-71, drawn to compounds, pharmaceutical compositions of compounds and method of using the compounds, wherein A being double bond, classified in class various, subclass various, depending on species election. If this group is elected, a further election of a single disclosed species is also required.

The inventions listed as Groups I and VIII do not relate to a single general inventive concept under 35 USC 121 or PCT Rule 13.1 because: **PCT Rule 13.1** states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). **PCT Rule 13.2** states that the unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

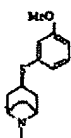
Annex B, **Part 1(a)**, indicates that the application should relate to only one invention, of if there is more than one invention, inclusion is permitted if they are so slinked to form a single general inventive concept. Annex B **Part 1(b)**, indicates that "special technical features" means those features that as a whole define a contribution over the prior art. Annex B **Part 1(c)**, further defines independent and dependent claims. Unity of invention only is concerned in relation to independent claims. Dependent claims are defined as a claim that contains all the features of another claim and is in the same category as the other claim. The category of a claim refers to the classification of claims according to subject matter e.g. product, process, use, apparatus, means, etc.

Annex B **Part 1(e)**, indicates that the permissible combinations of different categories of claims. **Part 1(e)I**, states that inclusion of an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product is permissible. Annex B, **Part 1(f)**, indicates the "Markush practice" of alternatives in a single claim. **Part 1(f)I**, indicates the technical relationship and the same or corresponding special technical feature is considered to be met when (A) all alternatives have a common property or activity, and (B) a common structure is present or al alternatives belong to a recognized class of chemical compounds. Further defining (B), Annex B, **Part 1(f)(I-iii)**, the common structure must; a) occupy a large portion of their structure, or b) the common structure constitutes a structurally distinctive portion, or c) where the structures are

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equivalent and therefore a recognized class of chemical compounds, each member could be substituted for one another with the same intended result. That is, with a common or equivalent structure, there is an expectation relationship and the corresponding special technical feature result from a common (or equivalent) structure that is responsible for the common activity (or property). **Part 1(f) iv**, indicates that when all alternatives of a Markush grouping can be differently classified, it shall not, taken alone, be considered justification for finding a lack of unity. **Part 1(f)v**, indicates that "When dealing with alternatives, if it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered by the examiner" In the instant case, at least one Markush alternative is not novel because prior art by WO 96/37226 anticipated group I, thus the lacking of unity of invention has been found.

During a telephone conversation with John Todaro on 02/15/2006 a provisional election was made without traverse to prosecute the invention of group I, claims 1-71, drawn to compounds, pharmaceutical compositions of compounds and method of using the compounds, wherein $A=(CH_2)_q$, $q=2$, $p=o=\Phi$, and $m=n=1$, with species election of Example 1, on pages 53-54, wherein,



. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-71, drawn to other Markush than group I, withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. **Priority**

This application is a 371 of PCT/US02/21296, filed on 07/29/2002, which claims benefit of 60/350,152, filed on 01/17/2002.

4. Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 68, and 70 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. V. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). These claims are withdrawn from consideration.

5. Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-4, 56, and 66-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-4 are rejected because the multiple references to a variable as defined in claim 1. See claim 3, line 3 is confusing. Please refer to a previous claim once as in claim 3, line 1. Correction is required.

Claim 56 is rejected because the term "R⁵" is confusing. Does it mean R⁵ in claim 50? Correction is required.

Claim 67 is rejected because the claim is vague and unclear. Are they claiming a compound or composition? Correction is required.

Claim 66 is rejected because the claims are self-conflicting. Pharmaceutical compositions by definition must be effective yet non-toxic. Claim 66 is pharmaceutical compositions without dosage limitation i.e. included both ineffective and toxic amount. It is recommended that "therapeutically effective amount" be incorporated in the claims.

6. *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 69, and 71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter, which was not describe in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claim 69 lacks description of the claim i.e. "modulator comprising administering an effective amount of a compound". An individual compound can either enhance or inhibit the receptor effect but not both

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simultaneously. Therefore, the specification lacks description of "modulation".

7. Claim 69 lacks description of the claim i.e. "treatment with a beta 4 subtype selective nicotinic receptor". Applicant has not shown the nexus for compounds 1-65 and treating any and all known or unknown diseases. In addition, what diseases are treatable or preventable compounds 1-65? Therefore, the specification lacks description of "treatment with a beta 4 subtype selective nicotinic receptor".

8. Claim 71 lacks description of the claim i.e. "treatment of dysfunctions of the central and autonomic nervous systems". Applicant has not shown the nexus for compounds 1-65 and treating any and all known or unknown diseases. In addition, what diseases are treatable or preventable compounds 1-65? Therefore, the specification lacks description of "treatment of dysfunctions of the central and autonomic nervous systems".

9. Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and

use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 69 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement because the specification does not enable the instant compound to alter the gene expression and therefore to treat any and all known or unknown diseases. The claim contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

1) The breadth of the claims.

2) The nature of the invention,

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- 3) The state of the prior art,
- 4) The level of one of ordinary skill,
- 5) The level of predictability in the art,
- 6) The amount of direction provided by the inventor,
- 7) The existence of working examples,
- 8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The nature of the invention: The instant invention is drawn to method of treatment of a condition indicating treatment with a beta 4 subtype selective nicotinic acetylcholine receptor modulator.

The state of the prior art: “ Neuronal nAChRs are widely distributed throughout the central and peripheral nervous systems where they modulate a number of CNS functions including neurotransmitter release and the control of cerebral blood flow. The hypothesis that cholinergic dysfunction contributes to cognitive impairments in patients with Alzheimer’s disease (AD) has prompted considerable exploration of potential therapies designed to replace lost cholinergic function, including acetylcholine (Ach) precursor loading, inhibition of Ach catabolism, and cholinomimetic treatments. We report a novel series of 3-pyridyl ether compounds which possess subnanomolar affinity for brain nAChRs and differentially activate subtypes of neuronal nAChRs.” (Journal of Medicine Chemistry, vol. 39, pages 817-825).

The state of the prior art is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific disease). There is no absolute predictability even in view of the seeming high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The predictability in the art: It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instantly claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to the therapeutic effects, whether or not the compounds of formula of claims 1-65 would be useful for treatment of a condition indicating treatment with a beta 4 subtype selective nicotinic acetylcholine receptor modulator.

Amount of guidance/working examples: Applicant provides no guidance for how a beta 4 subtype selective nicotinic acetylcholine receptor modulator could treat or any and all known or unknown diseases. Nor does applicant identify what diseases are treatable by a beta 4 subtype selective nicotinic acetylcholine receptor modulator.

There are no examples in the instant specification showing that the instant compounds modulate a beta 4 subtype selective nicotinic acetylcholine receptor. Nor are there any examples of the diseases being treated by a beta 4 subtype selective nicotinic acetylcholine receptor modulator.

The breadth of the claims: The breadth of claims is drawn to treating any and all known or unknown diseases associated with a beta 4 subtype selective nicotinic acetylcholine receptor.

The quantity of undue experimentation needed: Since the guidance and teaching provided by the specification is insufficient for treating diseases against which a beta 4 subtype selective nicotinic acetylcholine receptor, one of ordinary skill in the art, even with high level of skill, is unable to use the instant compounds as claimed without undue experimentation.

The level of the skill in the art: The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Taking all of the above into consideration, it is not seen where the instant claim 69, for treating or preventing diseases against which a

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regulation of gene expression is efficacious, have been enabled by the instant specification.

10. Claim 71 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement because the specification does not enable the instant compound to alter the gene expression and therefore to treat any and all known or unknown diseases. The claim contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

1) The breadth of the claims.

2) The nature of the invention,

- 3) The state of the prior art,
- 4) The level of one of ordinary skill,
- 5) The level of predictability in the art,
- 6) The amount of direction provided by the inventor,
- 7) The existence of working examples,
- 8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The nature of the invention: The instant invention is drawn to method of treatment of dysfunctions of the central and autonomic nervous systems using compounds of claims 1-65.

The state of the prior art: " Diabetes is associated with altered autonomic activity, and both the peripheral and central nervous content of NPY is altered in diabetes suggesting that part of the cardiovascular dysfunction of diabetes may be associated with altered responses to NPY. In diabetes rats NPY also decreased BF (blood flow) in the iliac and renal arteries but contrastingly increased BF in the superior mesenteric artery. We conclude that systemic NPY increases MAP (mean arterial pressure) as a result of decreased vascular conductance and this vasopressive effect of NPY is diminished in diabetes." (Peptides, Vol. 18, pages 809-815).

The state of the prior art is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological

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activities (i.e. what compounds can treat which specific disease). There is no absolute predictability even in view of the seeming high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The predictability in the art: It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instantly claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to the therapeutic effects, whether or not the compounds of formula of claims 1-65 would be useful for treatment of dysfunctions of the central and autonomic nervous systems.

Amount of guidance/working examples: Applicant provides no guidance for how treatment of dysfunctions of the central and autonomic nervous systems could treat or any and all known or unknown diseases. Nor does applicant identify what diseases are treatable by treatment of dysfunctions of the central and autonomic nervous systems.

There are no examples in the instant specification showing that the instant compounds control of dysfunctions of the central and autonomic nervous systems. Nor are there any examples of the diseases being

treated by controlling of dysfunctions of the central and autonomic nervous systems.

The breadth of the claims: The breadth of claims is drawn to treating any and all known or unknown diseases associated with controlling of dysfunctions of the central and autonomic nervous systems.

The quantity of undue experimentation needed: Since the guidance and teaching provided by the specification is insufficient for treatment of dysfunctions of the central and autonomic nervous systems, one of ordinary skill in the art, even with high level of skill, is unable to use the instant compounds as claimed without undue experimentation.

The level of the skill in the art: The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Taking all of the above into consideration, it is not seen where the instant claim 71, for treatment of dysfunctions of the central and autonomic nervous systems, have been enabled by the instant specification.

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Claim 67 is objected to under 37 CFR 1.75 as being a substantial duplicate of claims 1-65 or 66. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The preamble does not give patentable weight to the claim.

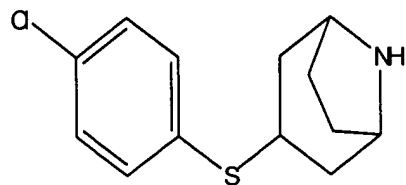
12.***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, and 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Chenard et al., WO 96/37226. Chenard et al. disclosed the instant claimed product, on page 43, Example 14, compound 3-(4-chlorophenylsulfanyl)-8-azabicyclo(3.2.1)octane

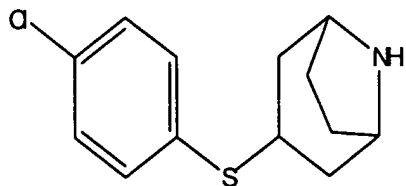


. Therefore, the instant claim is anticipated by

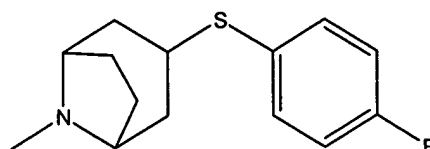
Chenard et al.

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13. Claims 1, and 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Chenard et al., US 6,046,213. Chenard et al. disclosed the instant claimed product, on column 51, preparation 41, compound 3-(4-chlorophenylsulfanyl)-8-azabicyclo(3.2.1)octane



and, on column 49, preparation 36, compound 3-(4-fluorophenylsulfanyl)-8-methyl-8-azabicyclo-(3.2.1)-octane

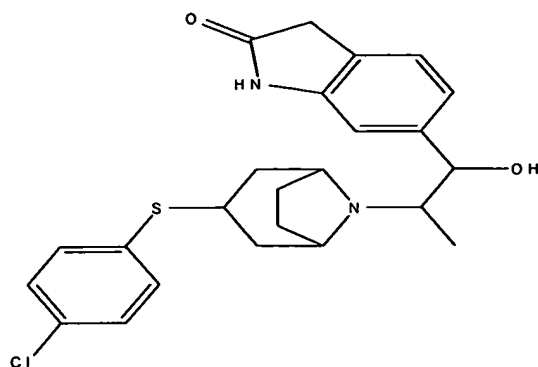


Therefore, the instant claim is anticipated by Chenard et al.

14. Claims 1, and 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Chenard et al., US 5,498,610. Chenard et al. disclosed the instant claimed product, on column 11, Example

13, 6-[2-(3-(4-chlorophenylthio)-8-azabicyclo[3.2.1]-oct-8-yl)-1-hydroxypropyl]-2(1H,3H)indolone

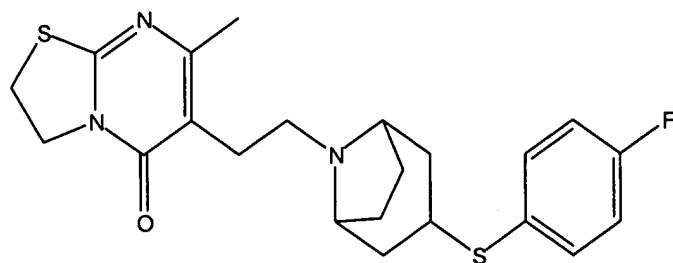
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, wherein R¹ being aryl alkyl in the instant claims. Therefore, the instant claim is anticipated by Chenard et al.

15. Claims 1, and 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Junichi et al., JP 04054181. Junichi et al. disclosed the instant claimed product, on page 673, compound 204 ,

5H-Thiazolo[3,2-a]pyrimidin-5-one, 6-[2-[3-[(4-fluorophenyl)thio]-8-azabicyclo[3.2.1]oct-8-yl]ethyl]-2,3-dihydro-7-methyl-

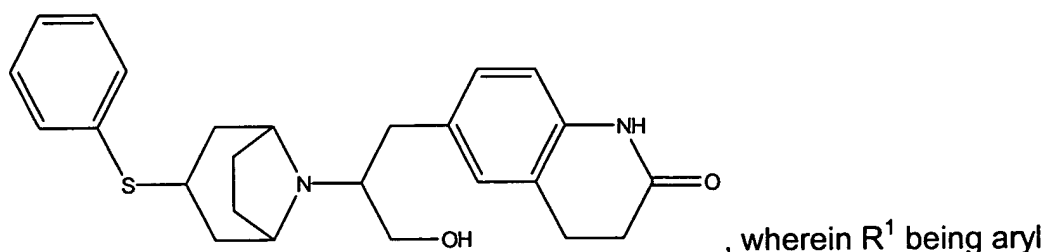


, wherein R¹ being aryl alkyl in the instant claims. Therefore, the instant claim is anticipated by Junichi et al.

16. Claims 1, and 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Chenard et al., US 5,306,723. Chenard et al. disclosed the instant claimed product, on column 11, Example 14, compound

6-[2-(3-phenylthio-8-azabicyclo[3.2.1]oct-8-yl)-1S-hydroxypropyl]-3,4-dihydro-2(1H)-quinolone

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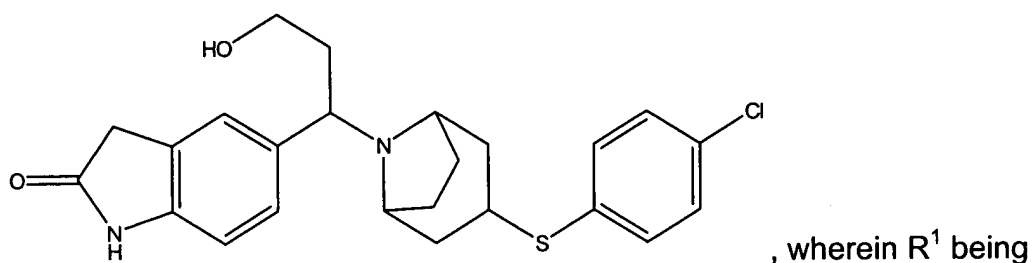


alkyl in the instant claims,

and on column 10, Example 13, compound

5-[2S-(3-(4-chlorophenylthio)-8-azabicyclo[3.2.1]oct-8-yl)-1S-

hydroxypropyl]-2(1H,3H)-indolone



aryl alkyl in the instant claims. Therefore, the instant claim is anticipated by Chenard et al.

17. **Claim Objections**

Claims 2, 7, 19-22, 30, 48-55 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani

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whose telephone number is 571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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